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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,958	01/05/2001	Manfred Auer	4-30730B/D1	6787

1095 7590 06/30/2003

THOMAS HOXIE  
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 06/30/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.

09/754,958

Applicant(s)

Auer et al

Examiner

Maurie G. Baker, Ph.D.

Art Unit

1639

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

THE REPLY FILED Jun 10, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: Please see attached.

3. ☒ Applicant's reply has overcome the following rejection(s):  
The reply would obviate some of the previous grounds of rejection under 35 USC 112, second paragraph if entered in future prosecution. Please see attached.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
Please see attached.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

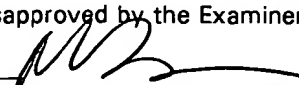
Claim(s) rejected: 12-16

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☐ Other: \_\_\_\_\_

  
MAURIE G. BAKER, PH.D.  
PRIMARY EXAMINER  
ART UNIT 1639

**ADVISORY ACTION***Attachment*

**Please note:** The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to Art Unit 1639.

1. Applicant's After Final amendment filed June 10, 2003 raises new issues which would require further consideration (rejection of proposed new claims) and does not place the case in better form for appeal or in condition for allowance. Thus the amendment will *not be entered*.
2. Applicant proposes to replace all of the pending claims with claims 17-21. Although newly proposed claims 17-21 would obviate *some* of the previous grounds of rejection under 35 USC 112, second paragraph (if entered in future prosecution), the newly proposed claims would be rejected under 35 U.S.C. 112, first paragraph for the same reasons as previous claims 12-16.
3. Applicant's arguments are moot in view of the non-entry of the amendment. Due to the non-entry of the amendment, all previous rejections are maintained for reasons of record. However, in the interest of compact prosecution, the following is addressed.
4. Applicants state that the examiner has mischaracterized the claims in two ways (Response, page 5). First, the examiner's statement that the claims "encompass an infinite number of variations" is stated to be incorrect. To be precise, the examiner stated

that “the claims could encompass an infinite number of variations” (emphasis added). In fact, to quote the examiner’s argument in whole:

The examiner’s position is that the definitions in the specification for the terms discussed in the rejection are *very broad*. This is not adequate description of the compounds as claimed, especially with respect to the linkages between each of the components. Thus the claims could encompass an infinite number of variations.

Thus the examiner maintains that, due to the absence of description of the linkages between each of the components, the claims could indeed encompass an infinite number of variations. It is also noted that the claims are open-ended.

5. Second, Applicants state that the examiner has mischaracterized the level of predictability in the art. The examiner respectfully disagrees. As stated in the enablement rejection, the examiner’s position is as follows:

Fluorescent conjugate compounds were well known at the time of filing; however, only limited numbers of such compounds were known and the specification gives no guidance to permit one of skill in the art to devise strategies for synthesis of *any* compound of formula (II – III) defined as “A-B-D-C-D’- (Formula (II))” and “A-B-D- and -D’-C (Formula (III))” that might have this function. The structures of possible variants are sufficiently diverse and one of ordinary skill would not be able to predict their structures. The limitation that the compounds comprise several linked fragments adds to the unpredictability because each portion of various structure would require completely different linkage strategies. Moreover, portions of the claimed compounds that are defined functionally could have a wide variety of structures with various sites that would be possible for linkage. One of ordinary skill could not guess, *a priori*, how to make and use **any** such compounds as one could not necessarily predict the linkage site and structure in the absence of any guidance without undue experimentation. Applicant’s claimed scope of compounds represents only an invitation to experiment regarding possible fragments (A, B, C, D and D’) with undefined structure and linkage sites.

Also, as stated in the written description rejection, the more unpredictable the art the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure. Regarding the comment on page 6 of the Response concerning Lilly and the statement that in chemical cases a generic formula "is normally an adequate description", it is noted that the claimed formulas are not truly generic but are completely open-ended (i.e. open to inclusion of any other portions, linked in any way).

6. Applicant refers to several issued patents on pages 5-6 of the Response.

However, whether similar claims have been allowed in other cases is immaterial, as stated by the PTO Board of Patent Appeals & Interferences in *Ex parte Balzarini* 21 USPQ 2d 1892 (1991):

Appellants have cited throughout this proceeding a number of U.S. Patents asserted to contain claims to treatment of humans suffering from AIDS using various anti-viral compounds in which evidence of in vivo testing was not submitted. However, it is well settled that whether similar claims have been allowed to others is immaterial. See *In re Giolito*, 530 F.2d 397, 188 USPQ 645 (1976).

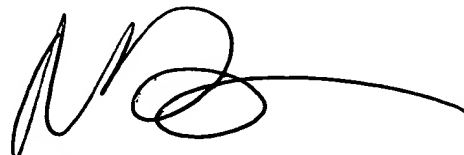
7. With respect to previous rejections B and D-G under 35 U.S.C. 112, second paragraph, the examiner maintains the claims are indefinite for the reasons set forth in the previous action. Note the following from MPEP 2173.02: If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973). Also, although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, applicant is directed to MPEP 2173.05(a): [t]he meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.  
June 27, 2003



MAURIE GARCIA BAKER PH.D.  
PRIMARY EXAMINER